Amendments to the Specification

Please replace paragraph 56, on page 12 of the specification as filed with the following paragraph:

[56] Figure 5 is a schematic block diagram depicting the hardware interface processor 205 associated with the bedside device 107. Hardware interface processor 205 comprises a micro controller 503 that communicates via a tri-state bus interface 501 to control blanking circuitry 301, sense electronics module 201, and stimulation electronics module 203. It also notifies signal processor 207 when data is available for further processing.

Please replace paragraph 65, on page 16 of the specification as filed with the following paragraph:

[65] An apparatus 1000 (e.g., the external device 950) is powered by a rechargeable/replaceable battery 1025 and is voltage regulated by a voltage regulation circuit 1019. A DSP controller 1005 processes neurological data from implantable device 953 and records/stores processed data in a boot flash memory 1007 or in a compact flash memory 1023, which extends the recording capability of memory 1007. The apparatus 1000 may be instructed by a user through buttons 1013. The corresponding inputted information is received by a peripheral interface control (PIC) microprocessor 1011 through a RS232 interface 1017. The user may instruct the DSP controller 1005 to process, store, and retrieve neurological data through PIC microprocessor 1011 ~~1005~~. The DSP controller 1005 is coupled to a memory 1009 and a speaker 1027. Also, the user may obtain information (e.g., status and selected processed data) through an LCD screen 1015.

Please replace paragraph 66, on page 16 of the specification as filed with the following paragraph:

[66] Figure 11 is a schematic block diagram of the implantable device 953 for the hybrid control system of Figure 9. An apparatus 1100 (e.g., the implantable device 953) is implanted in conjunction with a set of electrodes 1101. (In the exemplary embodiment shown in Figure 11, the set of electrodes 1101 comprises eight electrodes.) A reference electrode 1103 is another electrode that is not included in the set of electrodes 1101 and that is not typically involved with the neurological activity as the set of electrodes 1101. The apparatus 1100 communicates with the external device 1000 through a telemetry transceiver 1127 that is coupled to control registers 1109, an antenna 1125, and a telemetry link 1023. The apparatus 1000 (e.g., the external device 950) may collect data from the apparatus 1100 by placing a patch antenna 955 on the patient's body over the implantable device 953 to thereby communicate with antenna 1125 of the apparatus 1100.

Please replace paragraph 68, on page 17 of the specification as filed with the following paragraph:

[68] **IMPLANTED SYSTEM** – Figure 12 shows an embodiment of an implanted system 10 for treatment of a nervous system disorder in accordance with another embodiment of the invention. As discussed, although the implanted system 10 is discussed in the context of providing brain stimulation, it will be appreciated that the implanted system 10 may also be used to provide other treatment therapies at the brain or head or at other locations of the body. The implanted system 10 generally includes an implanted device 20 coupled to one or more therapy delivery elements 30. The therapy delivery elements 30, of course, may also serve as monitoring elements to receive a neurological signal. The implanted device 20 may continuously or intermittently communicate with an external programmer 23 (e.g., patient or physician programmer) via telemetry using, for example, radio-frequency signals. In this embodiment, each of the features and functionalities discussed herein are provided by the implanted device 20. As depicted, the external programmer 23 is coupled to a coil antenna 24 via wire 24a.

Please replace paragraph 73, on pages 18-19 of the specification as filed with the following paragraph:

[73] Figure 14 discloses one embodiment of such a relaying module in the form of a device that is worn, for example, on the patient's wrist. In such an arrangement, the implanted component 1405 of the medical device system communicates with the relaying module 1415 via telemetry antenna 1410. Similarly, the external component, which includes an external wearable signal processor 1425 that is coupled to audio output 1430 and is in communication with physician programmer 1435, communicates with the relaying module 1415 via antenna 1420. In the embodiment, a telemetry link 1421 between relaying module 1415 and antenna 1420 comprises a 3 MHz body wave telemetry link. To avoid interference, the relaying module 1415 may communicate with the external and implanted components using differing communication schemes. In some embodiments, the reverse direction and the forward direction of telemetry link 1421 may be associated with different frequency spectra. The relaying module 1415 thereby provides a greater range of communications between components of medical device system. For example, in the embodiment of the implanted system 10, the external programmer 23 may communicate with the implanted device 20 from a more remote location. The external programmer 23 may be across the room and still be in communication via the relaying module 1415. Similarly, in the embodiment of the hybrid system 1000, the external device 950 may be located further away than being worn by the patient. With the telemetry booster stage, the use of hybrid system 1000 is more convenient to the patient in particular at night while sleeping or when taking a shower, eliminating the need for the external device 950 to be worn on the body.

Please replace paragraph 76, on page 20 of the specification as filed with the following paragraph:

[76] Figure 15 shows a top-level flow diagram for a clock synchronization and calibration process 1500. For clarity, the following discussion is provided in the context of the external system 100, although other embodiments are possible. The process starts at step 1501 and in~~In~~ step 1503, a user initiates a study and sets-up the parameters through programmer 109 in step 1505. In the embodiment, the user enters a selected time (through programmer 109) that is different (which may be greater) than the reference time that is associated with monitoring equipment 105. (The reference time may comprise the associated date such month and day.) When the user determines that the time associated with monitoring equipment 105 equals the selected time, the user synchronizes the clocks in step 1507. Consequently, programmer 109 may generate a control message to bedside device 107 to synchronize the clock of bedside device 107. In the embodiment, the user selects an icon; however, other embodiments may use a Global Positioning System (GPS) clock reference or use a control line from monitoring equipment to activate the synchronization of clocks. In step 1509, programmer 109 determines if the clocks of bedside device 107 and programmer 109 were successfully synchronized and notifies the user through a real-time data display of programmer 109. In step 1511, the external system 100 starts run mode operation in which the medical device system may operate its intended functions.

Please replace paragraph 77, on page 21 of the specification as filed with the following paragraph:

[77] During the operation of the external system 100 over time, the clocks of monitoring equipment 105, programmer 109, and bedside device 107 may drift with respect to each other. In the embodiment, the clocks of programmer 109 and bedside device 107 are calibrated using the clock of monitoring equipment 105 as a reference. In step 1513, the programmer 109 notifies the user that calibration should be performed (e.g., every 12 hours, although other time periods may be utilized). The user consequently enters a selected time (through programmer 109) that is greater than the present time that is associated with monitoring equipment 105. When the user determines that the time associated with monitoring equipment 105 equals the selected time, the user calibrates the clocks in step 1513. With the calibration process, the clocks of bedside device 107 and programmer 109 are not modified. Rather a "drift" time (equal to the difference between the clock in bedside device 107 and monitoring equipment 105) is stored to a file. Data that are subsequently collected by bedside device 107 can be correlated to the time of monitoring equipment 105 by adjusting the time of bedside device 107 by the drift time. (In the embodiment, the drift time is determined by the difference between the current time of the second clock and the reference time of the first clock.) However, if the drift time is determined to be greater than a predetermined threshold (e.g., one second) in step 1515, programmer 109 may notify the user that the clocks need to be re-synchronized or more frequently calibrated to accurately track the drift between the clocks. If that is the case, the clocks are synchronized in step 1517. In step 1519, the operation is continued.

Please replace paragraph 78, on pages 21-22 of the specification as filed with the following paragraph:

[78] Figure 16 shows specific flow diagrams for clock synchronization and calibration in relation to Figure 15. Steps 1600, 1601, 1603, 1605, 1607 and 1609~~1601-1609~~ correspond to synchronizing the clocks in the external system 100 as shown in steps 1507 and 1517. Steps 1611, 1613, 1615, 1617 and 1619~~1611-1619~~ correspond to manually calibrating the clocks as shown in step 1513. Additionally, as shown in steps 1621, 1623, 1625, 1627 and 1629~~1621-1629~~, the external system 100 may periodically (e.g., every 10 minutes) calibrate the clocks of the programmer 109 and bedside device 107 without requiring intervention by the user. In step 1623, programmer 109 retrieves the time from bedside device 107. Programmer 109 compares its time with the retrieved time from bedside device 107 and calculates an updated drift time. Programmer 109 stores the adjusted drift time for correlating times subsequently. As discussed, synchronization may also be utilized in either the hybrid or implanted systems. For example, in the embodiment of the implanted system, the implanted device may provide to or receive from an external component (e.g., patient or physician programmer, video equipment, testing equipment) a clock synchronization/calibration signal, and the calibration/synchronization techniques discussed herein may be utilized to correspond the implanted device with the one or more external devices. Moreover, the clock reference (i.e., the reference clock to which all other clocks would be synchronized/calibrated) may be the clock in the implanted component, one of the external components, a GPS clock, an atomic clock, or any other reference clock.

Please replace paragraph 100, on page 31 of the specification as filed with the following paragraph:

[100] A time event 1907 corresponds to a clinical behavior onset time (CBOT), in which a patient manifests the symptoms of the neurological event (such as demonstrating the physical characteristics of a seizure). (In some cases, the patient may not manifest the symptoms even though an ITEO occurs.) Typically, if monitoring elements (such as electrodes) are appropriately positioned, the CBOT will occur after the ITEO. However, if the electrodes are placed away from a point of the neurological event, the CBOT may occur before the ITEO because of a delay of the neurological signals propagating through different portions of the patient's brain. A time event 1909 corresponds to an investigator seizure electrographic termination time (ISETT), in which the electrographic activity sufficiently decreases. As depicted, clinical seizure duration 1911 extends between the CBOT 1907 and ISETT 1909.

Please replace paragraph 101, on page 31 of the specification as filed with the following paragraph:

[101] To illustrate an embodiment of a screening procedure for a particular nervous system disorder, Figures 20 and 21 show flow diagrams for a seizure screening process to define treatment therapy according to an embodiment of the invention. Process 2000 comprises a baseline algorithm monitoring sub-process 2003 (comprising steps 2005-2049) and a trial screening sub-process 2151 (comprising steps 2153-2179). As depicted, the process 2000 starts at step 2001 and in~~In~~ step 2002, a physician implants electrodes into a patient in order to conduct process 2000.

Please replace paragraph 104, on page 32 of the specification as filed with the following paragraph:

[104] In step 2027, which comprises sub-steps 2029 and 2031, the correctness of electrode placement for seizure detection is verified. In sub-step 2029, the ITEO (investigator time of electrographic onset corresponding to time event 1903 in Figure 19) and the CBOT (clinical behavior onset time corresponding to time event 1907 in Figure 19) are provided to the medical device system. (In the embodiment, step 2027 is optional so that the clinician need not provide ITEO and CBOT to the medical device system.) In sub-step 2031, the medical device system determines if the ITEO did not occur after the CBOT. In the embodiment, the fact that the CBOT occurs before the ITEO is indicative that the selected electrodes are not sufficiently near the focus. In such a case, it can be determined to stop screening so that the process may end. ~~step 2032 determines whether to stop screening. If so, screening is ended in step 2034.~~ Otherwise, step 2002 ~~2004~~ allows the physician ~~physcian~~ to reposition subdural and/or DBS electrodes. The baseline algorithm monitoring sub-process 2003 is then repeated.

Please replace paragraph 106, on page 32 of the specification as filed with the following paragraph:

[106] Step 2041 determines whether to adapt the detection algorithm. If the detection algorithm is not adapted ~~not~~, step 2048, as describer later, is next executed. If the detection algorithm is adapted ~~so~~, step 2043 enables the physician to provide a training set (e.g., cluster data for previous seizures) so that the detection algorithm may enhance performance by adjusting its parameters. ~~.~~ The use of filter adaptation for detecting seizures is disclosed in U.S. Patent No. 5,995,868 entitled "System for the Prediction, Rapid Detection, Warning, Prevention, or Control of Changes in Activity States in the Brain of a Subject" and is incorporated herein in its entirety. In sub-step 2043, the physician identifies collected neurological data that characterizes the seizure (e.g., one or more detection clusters that are associated with the seizure). The detection algorithm may be adapted using different methods, as requested by the physician or automatically (unsupervised learning). With one variation of the embodiment, the detection algorithm, in step 2045 ~~2044~~, is adapted by adjusting threshold and time duration settings in order to approximately optimize seizure detection in relation to the data identified in sub-step 2043. In step 2047 ~~2045~~, the physician evaluates the adaptation results. In step 2047 ~~2046~~, if the adaptation is satisfactory, the physician may accept recommended settings through an input device in step 2047. However, if the adaptation is not satisfactory, as determined in step 2047 ~~by step 2046~~, the physician may reject the recommended settings. In step 2048, it is ~~executed to~~ determined whether to record more seizures. If more seizures need to be recorded ~~so~~, baseline algorithm monitoring sub-process 2005 ~~2003~~ continues to execute for subsequent seizures. Otherwise, process 2000 proceeds to trial screening sub-process 2151.

Please replace paragraph 109, on page 34-35 of the specification as filed with the following paragraph:

[109] If the physician indicates that the stimulation settings and the electrode configuration should be used, the medical device system applies treatment in step 2167. The medical device system or the physician determines whether the therapy is considered successful in step 2168 by a set of criteria. In the embodiment, the medical device system determines if there is a sufficient reduction of a detected frequency, duration, intensity, and extent of the electrographic spread that are associated with the seizure. If successful, in step 2173 the trial screening is ended and in step 2175 the leads may be internalized and the IPG may be implanted.

Please replace paragraph 117, on page 38 of the specification as filed with the following paragraph:

[117] The medical device system may also ensure other efficacy criterions are satisfied for any user-defined treatment therapy configuration. For example, the medical device system providing stimulation therapy may ensure that the polarities of the stimulation pulses are properly defined, e.g., all polarities cannot be off and that the voltage level is greater than zero on at least one stimulation channel, and that at least one cathode and at least one anode are configured.